

**JUN 24 2003****AN ENDOVASCULAR COMPANY**

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4600 Nathan Lane North, Plymouth, MN 55442-2920

**510(k) Summary**  
**K031864**

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

<b>Submitter</b>	EV3 4600 NATHAN LANE NORTH PLYMOUTH, MN 55442
<b>TRADE NAME</b>	Nitrex™ Nitinol Guidewire
<b>GENERIC CLASS</b>	Guide wire
<b>CLASSIFICATION</b>	Class II (21 CFR 870.1330)
<b>SUBMITTED BY</b>	ev3 Inc 4600 Nathan Lane Minneapolis, MN 55442
<b>CONTACT</b>	Carolyn Anderson Regulatory Affairs Specialist 763-398-7487
<b>PREDICATE</b>	Ultra-Select guidewire (K910280) FlexFinder guidewire (K893626, K943390) Nitrex Nitinol Guidewire (K024021)
<b>DEVICE DESCRIPTION</b>	The guidewire is constructed of nitinol (nickel-titanium alloy). The nitinol core extends from the distal tip of the guidewire to the proximal shaft end. The distal tip is a helically coiled coil gold plated tungsten wire. The guidewire is coated with a coating(s) to help facilitate smooth passage.
<b>INDICATION FOR USE</b>	The 0.035" and 0.025" Guidewire is indicated for use in the peripheral vasculature. The 0.014", 0.016", and 0.018" guidewires are indicated for use in the peripheral and coronary vasculature.
<b>TESTING</b>	Dimensional inspection of the guidewire has been conducted. All testing of the product yielded acceptable results. A review of the verification/validation testing performed on the original device determined that the modification would not affect the original results.
<b>SUMMARY OF SUBSTANTIAL EQUIVALENCE</b>	The Nitrex™ Nitinol Guidewire is substantially equivalent to the predicate device in intended use, materials, labeling and principles of operation.

**CONFIDENTIAL**  
Nitrex Nitinol Guidewire, Modified



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 24 2003

EV3 Corporation  
c/o Ms. Carolyn Anderson  
Regulatory Affairs Specialist  
4600 Nathan Lane  
Plymouth, MN 55442

Re: K031864  
Nitrex™ Nitinol Guidewire  
Regulation Number: 21 CFR 870.1330  
Regulation Name: Wire, Guide, Catheter  
Regulatory Class: Class II (two)  
Product Code: DQX  
Dated: June 13, 2003  
Received: June 16, 2003

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

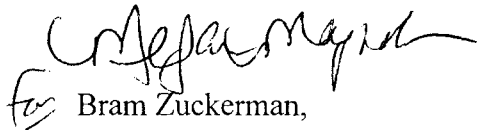
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram Zuckerman". To the left of the signature is a small, stylized mark that looks like "for".

Bram Zuckerman,  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

JUN 24 2003

## INDICATIONS FOR USE STATEMENT

510 (k) Number (if known): K031864

Device Name: Nitrex™ Nitinol Guidewire

Indications For Use: The 0.035" and 0.025" Guidewire is indicated for use in the peripheral vasculature. The 0.014", 0.016", and 0.018" guidewires are indicated for use in the peripheral and coronary vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. J. M. for B. Zuckerman  
(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K031864

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-the-Counter